

REMARKSClaim Amendments

Claim 1 has been amended to recite that the pharmaceutical composition comprises a unit dosage form of an effective amount of a polydiallylamine homopolymer substantially free of alkylation and a pharmaceutically acceptable carrier. Support for this amendment can be found at page 14, line 8 of the Specification. Claims 7 and 8 are newly added and are directed to a pharmaceutical composition which is in tablet form (Claim 7) or in capsule form (Claim 8). Support for newly added Claims 7 and 8 can be found at page 14, line 8 of the Specification.

Rejection of Claims 1 and 4-6 Under 35 U.S.C. § 102 (b)

The Examiner rejected Claims 1 and 4-6 under 35 U.S.C. § 102(b) as being anticipated by Butler *et al.* (U.S. Patent No. 2,926,161). In particular, the Examiner stated that Butler *et al.* teach polymers of diallylamine with R=H, a salt and water. Applicants respectfully disagree that Butler *et al.* teach the pharmaceutical composition of Applicants' claims, particularly as amended. As a preliminary matter, Applicants assume that the Examiner is referring to U.S. Patent No. 2,926,161 to Butler *et al.*, rather than U.S. Patent No. 3,288,770 to Butler (also of record) despite the reference to Col. 15 of Butler *et al.* which does not exist. If Applicants' assumption is incorrect, clarification is requested in the next Communication from the Office.

Applicants' claims as amended are directed to a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer which is substantially free of alkylated amine monomer and a pharmaceutically acceptable carrier. As set forth in the Specification, the pharmaceutical composition can be used as a bile acid sequestrant for the treatment of hypercholesterolemia, atherosclerosis and/or reduction of serum cholesterol.

Butler *et al.* teach a polydiallylamine thermoplastic polymer. The polymers of Butler *et al.* are useful as film and fiber forming materials. The polymeric films and fibers taught by Butler *et al.* exhibit resistance to burning and fuel oils and are also able to be further derivatized to amides which are also useful in the fiber industry.

However, Butler *et al.* do not teach or suggest that the polydiallylamine homopolymers can be present in a pharmaceutical composition in a unit dosage form (e.g., a tablet or a capsule)

at an effective amount. Films and fibers of an unspecified weight would not be considered by a person of skill in the art to be a "unit dosage form." The Examiner refers to Col. 3, lines 39-40 of Butler *et al.* which specifies water, presumably to address the presence of a "pharmaceutically acceptable carrier." The water which the Examiner refers to is used to provide a solvent for the polymerization reaction used to prepare the polymers described. Certainly, the mixture of monomers, polymers and other materials in a reaction flask in the presence of laboratory grade water does not anticipate Applicants' claimed pharmaceutical composition to be administered to patients. The water, in this context, is not "pharmaceutically acceptable." The contents of the flask is not in "a unit dosage form." This composition is simply, not a pharmaceutical.

The Examiner's reference to salt is not completely understood as there is no Col. 15 present in Butler *et al.* In any event, a teaching of a salt of the polydiallylamine polymers of Butler *et al.* does not anticipate a pharmaceutical composition comprising a unit dosage form of an effective amount of a homopolymer of polydiallylamine which is substantially free of alkylation and a pharmaceutically acceptable carrier. There is no teaching in Butler *et al.* of a dosage form (e.g., a capsule or tablet), no teaching of what would be an effective amount in a pharmaceutical composition or of what might be a pharmaceutically acceptable carrier. As such, Butler *et al.* fail to provide a teaching of a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer and a pharmaceutically acceptable carrier. In other words, it is clear that the reference has not placed Applicants' claimed pharmaceutical composition in the possession of the public and as such, does not anticipate the claimed invention.

In view of the above, Applicants' claims, particularly as amended, meet the requirements of 35 U.S.C. § 102(b) and are patentable over the teachings of Butler *et al.*

#### Rejection of Claims 2 and 3 Under 35 U.S.C. § 102 (b)

The Examiner has rejected Claims 2 and 3 under 35 U.S.C. § 102 (b) as being anticipated by Van Eenam. In particular, the Examiner stated that Van Eenam teaches reacting polydiallylamine with and epihalohydrin, wherein R=H. The Examiner further stated that water is disclosed. Applicants respectfully disagree that Van Eenam teach or suggest Applicants' claims pharmaceutical composition.

As discussed above, Applicants' claims as amended are directed to a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer which is substantially free of alkylated amine monomer and a pharmaceutically acceptable carrier. As set forth in the Specification, the pharmaceutical composition can be used as a bile acid sequestrant for the treatment of hypercholesterolemia, atherosclerosis and/or reduction of serum cholesterol.

Van Eenam teach a process for the production of acid stabilized resin solutions. The process comprises polymerizing a diallylamine salt, separating unreacted monomer from the reaction mixture, treating the diallylamine polymer with epihalohydrin and adding an acid to stabilize the resin. The aqueous resin solutions are useful for applying to paper and other felted cellulosic products to impart wet and dry strength characteristics thereto.

Van Eenam do not teach Applicants' claimed pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer which is substantially free of alkylation and a pharmaceutically acceptable carrier. In fact, Van Eenam add little to the teachings of Butler *et al.* discussed in detail above.

The Examiner refers to Col. 1, line 46 as disclosing water. The water which the Examiner refers to at Col. 1 of Van Eenam provides the solvent for the polymerization reaction of the process described. Certainly, the use of laboratory grade water in a mixture of crude polymer and epihalohydrin does not teach Applicants' claimed pharmaceutical composition. Other references to a water/polymer mixture found in Van Eenam also refer to the mixture of reactants used in the claimed process or to a suspension for application to paper.

As such, Van Eenam fails to provide a teaching of a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer and a pharmaceutically acceptable carrier. In other words, it is clear that the reference has not placed Applicants' claimed pharmaceutical composition in the possession of the public and as such, does not anticipate the claimed invention. That is, a teaching of a dosage form (e.g., a capsule or tablet), of an effective amount in the pharmaceutical composition and a pharmaceutically acceptable carrier are not found in Van Eenam.

In view of the above, Applicants' claims, particularly as amended, meet the requirements of 35 U.S.C. § 102(b) and are patentable over the teachings of Van Eenam.

Rejection of Claims 1-6 For Obviousness-Type Double Patenting

The Examiner has rejected Claims 1-6 for Obviousness-Type Double Patenting over Claims 16-25 of commonly-owned U.S. Patent 6,365,186. Applicants will file a Terminal Disclaimer upon an indication of allowable subject matter.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

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MARKED UP VERSION OF AMENDMENTS

Specification Amendments Under 37 C.F.R. § 1.121(b)(1)(iii)

Replace the Title at pages 1 and 28 with the below Title marked up by way of bracketing and underlining to show the changes relative to the previous version of the Title.

[COMBINATION THERAPY] A PHARMACEUTICAL COMPOSITION FOR TREATING  
HYPERCHOLESTEROLEMIA

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

1. (Amended) A pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallylamine homopolymer, said homopolymer characterized in that the polymer is substantially free of alkylated amine monomers and a pharmaceutically acceptable carrier.